

A vertical photograph on the left side of the slide shows several pieces of laboratory glassware, including test tubes and beakers, in a laboratory setting. The image is slightly blurred, focusing on the foreground glassware.

# How to Implement a Monitoring Program to Increase Business Value

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## Panelists:

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# Recent Industry Headlines

ENFORCEMENTS, GOVERNMENT ACTION, & SALES CHALLENGES

HuronLifeSciences

Medical devices company settles lawsuit

Stryker paid \$26.8M to doctors

**FDA Reaches \$1M Settlement with Medical Device Company**

LAW | March 5, 2013, 2:26 p.m. ET

## Par Pharmaceutical to Settle Off-Label Charges

## U.S. Accuses Novartis of Kickbacks

*Prosecutors Allege Drug Maker Gave Physicians Lavish Dinners, Fishing Trips to Prescribe Pills*

THE TEXAS TRIBUNE

Payments to Doctors by Pharmaceutical Companies Raise Issues of Conflicts

**DOLLARS FOR DOCS**

How Pharma Money Influences Physician Prescriptions



Pharmaceutical giant Sanofi settles charges it gave doctors kickbacks

NEWS IN BRIEF

Novartis to reduce US sales force, days after denying job cut rumours

## Is Your Doctor on Big Pharma's Payroll?

THE WALL STREET JOURNAL

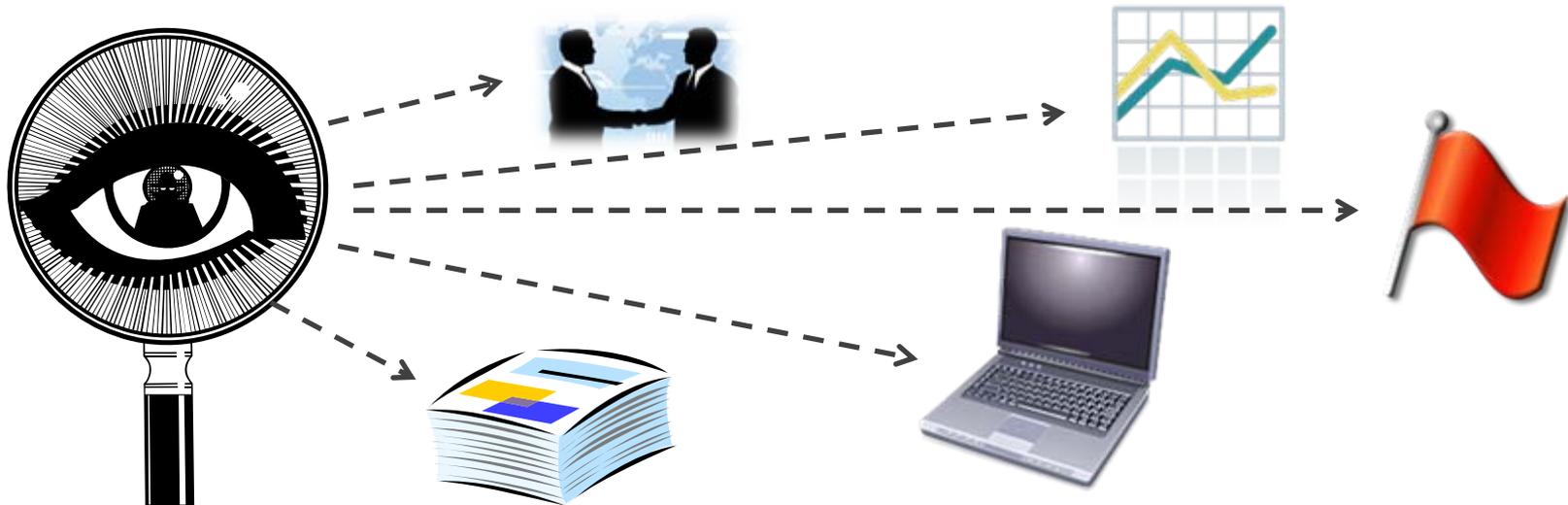
*...drug makers have been cutting their conventional sales forces. By the end of 2008, the number of U.S. sales reps had dropped to 90,000 from a peak of about 106,000 in 2006...*

# What is Monitoring?

*Monitor (according to Webster):*

*to watch, keep track of, or check usually for a special purpose*

*Monitoring is the ongoing, near-time analysis of traditional and non-traditional data sources, related to targeted business activities and controls, to proactively identify, trend and respond to potential compliance "signals" and to be predictive of customer behavior.*



Trends motivating monitoring activities:

- Corporate Integrity Agreements (CIAs)
- Industry scrutiny
- Best Practices
  - ☑ *Collaboration with the business*
  - ☑ *Proactive approach*
  - ☑ *Intelligence into the business*



There are usually four components to a CIA monitoring requirement, collectively referred to as the Field Force Monitoring and Review Efforts. The components are as follows:

1. **Speaker Program Monitoring**
2. **Sales Representative Observations (Ride-Alongs)**
3. Records Review
4. Reporting and Follow-up

■ The speaker program and observation requirements tend to vary from company to company. Requirements have ranged from 50 to 150 speaker programs per reporting period.

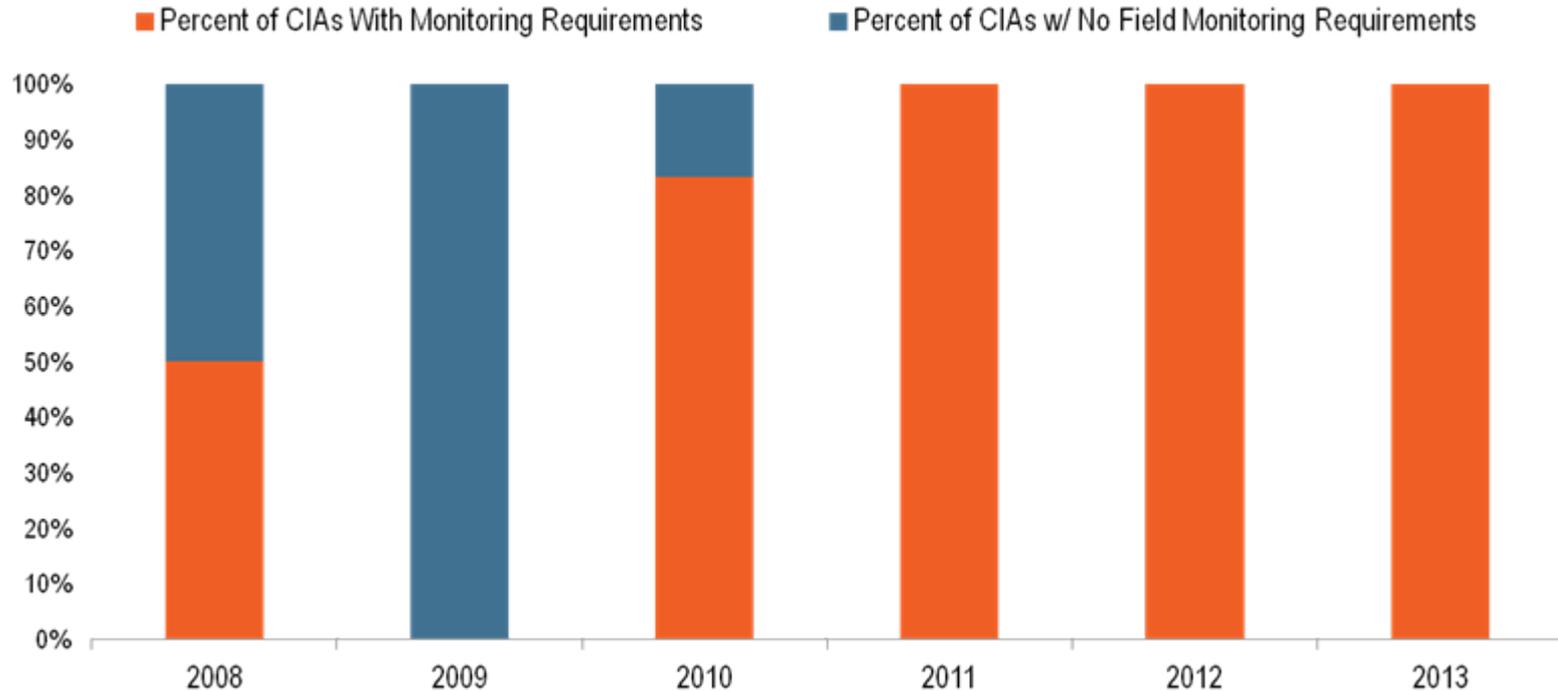


VS



- Since 2011, all CIA's for pharmaceutical companies require field monitoring activities:

## Trend in Field Monitoring Requirements



Data source: U.S. Department of Justice  
Huron Proprietary Analysis

# What do you gain from Monitoring?

- ☑ Advance your Compliance program
- ☑ Prevent, detect, and resolve
- ☑ Manage risk
- ☑ Increase visibility
- ☑ Increase partnerships with the business
- ☑ Improve training
- ☑ Identify gaps and improve processes
- ☑ Identify trends and escalate findings to relevant stakeholders

# How to Implement a Monitoring Program

## FOUR MAIN STEPS

1

Initial  
Program  
Setup



2

Pre-  
monitoring



3

Live  
Monitoring



4

Post-  
monitoring



# Step 1: Initial Program Setup

## DEFINING THE PROCESS



### Develop a project charter

- Project team
  - Development team
  - Monitoring team (internal, external, or hybrid)
- Roles and responsibilities



### Determine funding



### Understand the data



### Monitor Training



### Communication to the company



### Selection process

- Speaker Programs
- Ride-Alongs



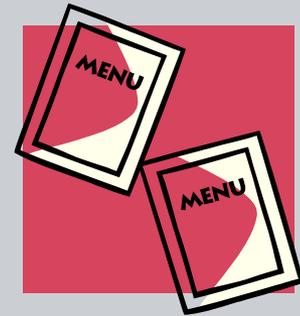
### Establish escalation process

# Step 2: Pre-Monitoring Activities

PRIOR TO GOING INTO THE FIELD

## Speaker Programs

- Inform sales representative
- Monitor contact representative
- Determine logistics
- Schedule a back-up program
- Review attendees
- Set expectations and answer representative questions



## Ride-Alongs

- Inform sales representatives
- Monitor contact representative
- Determine logistics
- Pre-call planning meeting
- Set expectations and answer representative questions



# Step 3: Live Monitoring

## WHAT TO LOOK FOR

### Speaker Programs

- Appropriate program venue
- Presentation
- Program materials
- Interaction with audience and speaker – effectiveness of program/ speaker



### Ride-Alongs

- Set expectations
- List of HCPs
- Review of promotional materials
- Individual HCP assessment or summary of the day

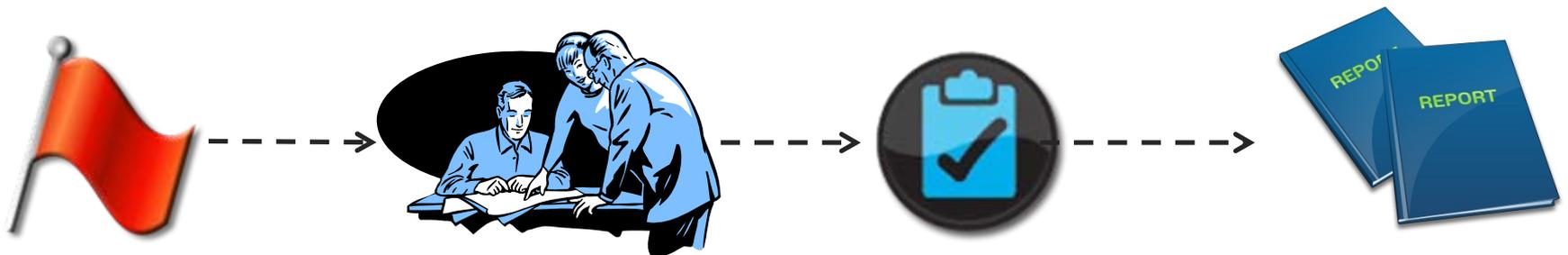


*TIP: In either scenario, review the event against criteria pre-determined on an easy-to-use evaluation form that captures all the regulatory requirements*

# Step 4: Post-Monitoring

## CLOSING THE PROGRAM?

- Were any issues identified?
  - Consider having issue routing protocol for each of the questions on your evaluation form
- Follow-up on issues and close the loop
  - Incorporate your findings into future training and communications
- Reporting
  - Trending analysis and management reporting
  - Data collection and review



# Collaboration with the Business

## BUILDING RELATIONSHIPS

- Demonstrate Compliance's support of business objectives
  - Gather Sales and Marketing management input on interactions with sales representatives before and during monitored events
  - Understand the business' pain-points and concerns with products
  - Tie key business objectives into the monitoring process, if possible
- Help ensure that the sales force does not feel undue pressure
  - Communicate program objectives and set expectation with DMs and RMs prior to the start of the program
  - Include Sales and Marketing management in planning stages
    - Explain what will be evaluated
    - Address questions or concerns
- Encourage open communication with the entire sales force
  - Learning opportunity for all
  - Understand their frustrations and work together to resolve them



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